

### **REMARKS**

Claims 1-15 are presently pending in the application.

The Examiner has rejected claims 1-15 under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner argues that the statement, “the titanium nitride coating has a larger surface on its side remote from the electrode surface” is not understood, and that the exact location of where this is and exactly what is meant in light of Fig. 1a is not unclear. Applicants respectfully traverse this rejection as follows. As shown in Fig. 1a, the surface area of titanium nitride on the top (remote from the electrode surface) is larger than that on the bottom due to the hills and the valleys. This aspect of the invention may be further understood by considering the diagram attached hereto, which clearly illustrates the hills and valleys, resulting in a larger surface area of TiN on the side away from the electrode surface. Applicants thus submit that claims 1-15 are understandable and enabled, and accordingly request reconsideration and withdrawal of the § 112 rejection.

#### **Prior Art Rejections Under §§102(b) and 103(a)**

The Examiner has rejected claims 1-8 and 10-13 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,430,448 of Chitre et al. (“Chitre”). Further, claims 1-13 and 15 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Chitre in view of U.S. Patent No. 4,679,72 of Baker Jr. (“Baker Jr.”). Finally, claims 12-14 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Chitre in view of Baker Jr. and further in view of U.S. Patent No. 4,603,704 of Mund et al. (“Mund”). Applicants respectfully traverse these rejections and the arguments in support thereof as follows, and respectfully request reconsideration and withdrawal of the rejections.

#### **Rejection Under § 102(b) Based on Chitre**

The Examiner argues that Chitre anticipates claims 1-8 and 10-13, which Applicants respectfully traverse as follows. The present invention is directed to a stimulation electrode having an electrode surface which is at least partially covered with a coating of titanium nitride (TiN). As clearly shown in the attached diagram, which illustrates one embodiment of the

invention, the TiN coating has a larger surface area on the side away from the electrode surface than the region of the electrode surface covered with the titanium nitride due to the hills and valleys. The titanium nitride layer is further covered with at least one oxidation protection layer which is substantially non-porous at least on the side facing the titanium nitride (see paragraph [0010] of specification). The resulting stimulation electrode provides a sufficient lifetime in anodic operation. Further, the use of the oxidation protection layer leads to complete prevention or at least substantial slowing of the formation of oxide layers in the region of the stimulation electrode.

In contrast, Chitre describes an implantable stimulation electrode containing a metal substrate having an exposed outer surface covered with an inner layer of titanium nitride and an outer layer of platinum black. As shown in Figure 3A, only the top end of the electrode assembly contains the layers of titanium nitride and platinum black. However, Chitre does not teach or suggest a substantially non-porous oxidation protection layer on the titanium nitride. Rather, the platinum black coating used by Chitre is inherently porous, which would reduce the lifetime of the resulting device. Further, in contrast with the present invention, Chitra also does not teach or suggest that the titanium nitride coating has a larger surface area on its side remote from the electrode surface than the region of the electrode surface covered with the titanium nitride. No uneven or textured surface is taught or suggested, such as the hills and valleys shown in Fig. 1. Rather, the TiN surface of Chitre is smooth, which would result in higher impedance than in the inventive device.

For all of these reasons, Chitre does not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 102(b) rejection are respectfully requested.

*Rejection Under § 103(a) Based on Chitre In View of Baker Jr.*

Regarding claims 1-13 and 15, the Examiner argues that Chitre discloses an electrode assembly having a tip constructed of a layer of titanium nitride and an outcoating of platinum black. The Examiner acknowledges that Chitre does not disclose the claimed layer of iridium oxide. However, Baker Jr. allegedly teaches that iridium oxide is an exceptional alternative to platinum black as an electrode coating. The reference also allegedly teaches the use of sputtering to deposit the material and notes the use of the electrode for an anode. The Examiner concludes that given the teaching of Baker Jr., it would have been obvious to one having ordinary skill in

the art to use iridium oxide in place of the platinum black in Chitre to provide a better coating. Further, the Examiner contends that to use the device as an anode and deposit the material by sputtering would have been obvious given that the use is old and that sputtering is well known in the art for applying a coating. Applicants respectfully traverse this rejection as follows.

As previously explained, Chitre does not teach or suggest the claimed electrode having a larger surface area of platinum black on the side remote from the electrode surface, nor the substantially non-porous oxidation protection layer on the surface of the platinum nitride. Further, even the proposed combination with Baker Jr. does not cure these deficiencies.

Baker Jr. discloses that the use of an iridium oxide layer on the surface of a stimulating cathode in a cardiac pacemaker results in a reduction in the stimulation threshold relative to an uncoated electrode (col. 3, lines 14-18). However, Baker does not address the improvement in utilizing iridium oxide for solving the anodic problems to which the present invention is directed, namely the formation of oxide layers which causes a rise in impedance and a rise in threshold voltage. Further, Baker Jr. teaches that the surface of an electrode tip of metal is coated with a film or layer of iridium oxide (col. 7, lines 6-25). However, Baker does not refer to a first coating of titanium nitride and thus certainly does not teach or suggest a titanium nitride coating having a larger surface area on the side remote from the electrode surface than the region covered with TiN. Additionally, in contrast with the present invention, Baker does not teach an oxidation protection layer. Rather, Baker uses iridium oxide solely to perform as a charge flow transducer between media exhibiting different charge flow mechanisms (col. 4, lines 35-37).

Finally, there would be no motivation for one skilled in the art to combine Baker Jr. and Chitre as proposed by the Examiner. Baker Jr. relates to coating of a metal electrode (col. 5, lines 40-43) whereas Chitre teaches a titanium nitride coating on an electrode surface which is covered with platinum black. Accordingly, there would be no motivation to replace the platinum black of Chitre, used to cover a titanium nitride coating, with the iridium oxide coating of Baker Jr., taught to be effective at coating metal electrode surfaces, nor any reasonable expectation of success.

For all of these reasons, even the proposed combination of Chitre and Baker Jr., if proper, would not teach or suggest all of the claimed elements, and reconsideration of the § 103(a) rejection based on Chitre in view of Baker Jr. are respectfully requested.

*Rejection Under § 103(a) Based on Chitre in view of Baker Jr. and Mund*

Finally, regarding claims 12-14, the Examiner argues that Mund teaches that stimulating electrodes used in pacemakers also have application in nerve and muscle stimulators. Given this teaching, the Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time of the invention to use the pace making electrodes of Chitre or the proposed combination of Chitre and Baker Jr. as a nerve stimulator. Applicants respectfully traverse this rejection as follows.

As previously explained, even the proposed combination of Chitre and Baker Jr. would not teach or suggest all of the elements of the independent claim, and even the proposed combination with Mund would not cure these deficiencies.

Specifically, Mund discloses an electrode for medical application comprising an electrode. In one embodiment, a porous layer may be applied over a dense non-porous sealing layer of the same material as the porous layer (col. 4, lines 58-61). The materials used to form such coatings may include carbides, nitrides, or carbonitrides of titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum, or tungsten (col. 4, lines 48-51). Accordingly, in one embodiment, an electrode contains a non-porous TiN coating covered with a porous TiN coating.

In contrast, the present invention requires that the titanium nitride layer be covered with at least one oxidation protection layer, in which at least the side of the oxidation protection layer facing the titanium nitride is substantially non-porous. Mund does not teach or suggest a substantially non-porous oxidation protection layer on top of a titanium nitride layer.

For these reasons, even the proposed combination of Chitre, Baker Jr., and Mund, if proper, would not teach or suggest all of the claimed elements. Accordingly, reconsideration of the § 103(a) rejection based on Chitre in view of Baker Jr. and Mund is respectfully requested.

In conclusion, for the Examiner's convenience, the following Table demonstrates the different features exhibited by the present invention and the cited prior art. From this Table, it can be clearly seen that there would be no motivation to combine the cited references and that, even if such combinations were proper, they would not result in the present invention.

Present Invention	Chitre	Baker Jr.	Mund
electrode TiN non-porous protection layer	electrode TiN porous Pt black layer	electrode IrO	electrode non-porous TiN porous TiN

In view of the preceding Remarks, it is respectfully submitted that the pending claims are in compliance with § 112, patentably distinct from the prior art of record, and in condition for allowance. A Notice of Allowance is respectfully requested.

· Respectfully submitted,

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(Date)

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Enclosure- Petition for Extension of Time (one month)

Attachment- Diagram of Inventive Stimulation Electrode



## Attachment – Diagram of Inventive Stimulation Electrode

